

SANGAMO BIOSCIENCES INC  
Form 10-Q  
May 09, 2008  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

**☐ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 2008

OR

**☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-30171

**SANGAMO BIOSCIENCES, INC.**

(exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**68-0359556**  
(IRS Employer  
Identification No.)

**501 Canal Blvd, Suite A100**

**Richmond, California 94804**

(Address of principal executive offices)

**(510) 970-6000**

(Registrant's telephone number, including area code)

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by section 13 or 15(d) of the Securities Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of April 29, 2008, 40,815,404 shares of the issuer's common stock, par value \$0.01 per share, were outstanding.

**Table of Contents**

**INDEX**

**SANGAMO BIOSCIENCES, INC.**

**PART I. FINANCIAL INFORMATION**

Item 1. Financial Statements (Unaudited)

Condensed Consolidated Balance Sheets at March 31, 2008 and December 31, 2007

Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2008 and 2007

Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2008 and 2007

Notes to Condensed Consolidated Financial Statements

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Item 4. Controls and Procedures

**PART II. OTHER INFORMATION**

Item 1. Legal Proceedings

Item 1A. Risk Factors

Item 6. Exhibits

**SIGNATURES**

**CERTIFICATIONS**

*Some statements contained in this report are forward-looking with respect to our operations, research and development activities, operating results and financial condition. Statements that are forward-looking in nature should be read with caution because they involve risks and uncertainties, which are included, for example, in specific and general discussions about:*

*our strategy;*

*product development and commercialization of our products;*

*clinical trials;*

*revenues from existing and new collaborations;*

*sufficiency of our cash resources;*

*our research and development and other expenses;*

*our operational and legal risks; and*

*our plans, objectives, expectations and intentions and any other statements that are not historical facts.*

Various terms and expressions similar to them are intended to identify these cautionary statements. These terms include: anticipates, believes, continues, could, estimates, expects, intends, may, plans, seeks, should and will. Actual results may differ materially from the

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

implied in those statements. Factors that could cause these differences include, but are not limited to, those discussed under Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations. Sangamo undertakes no obligation to publicly release any revisions to forward-looking statements to reflect events or circumstances arising after the date of this report. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q.

**Table of Contents****PART 1. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****SANGAMO BIOSCIENCES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share amounts)**

	<b>March 31, 2008 (unaudited)</b>	<b>December 31, 2007 (1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,942	\$ 12,275
Marketable securities	63,468	68,813
Interest receivable	169	324
Accounts receivable	613	209
Prepaid expenses	517	497
Total current assets	74,709	82,118
Property and equipment, net	2,021	1,770
Other assets	12	12
Total assets	\$ 76,742	\$ 83,900
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 4,112	\$ 3,538
Accrued compensation and employee benefits	742	1,199
Deferred revenues	3,730	4,944
Total current liabilities	8,584	9,681
Deferred revenues, non-current portion	1,701	2,097
Total liabilities	10,285	11,778
Stockholders equity:		
Common stock, \$0.01 par value; 80,000,000 shares authorized, 40,793,172 and 40,315,368 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively	408	403
Additional paid-in capital	223,368	221,176
Accumulated deficit	(157,724)	(149,752)
Accumulated other comprehensive income	405	295
Total stockholders equity	66,457	72,122
Total liabilities and stockholders equity	\$ 76,742	\$ 83,900

Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

- (1) Amounts derived from Audited Consolidated Financial Statements dated December 31, 2007 filed as a part of our 2007 Annual Report on Form 10-K.

*See accompanying notes.*

**Table of Contents****SANGAMO BIOSCIENCES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except per share amounts)****(Unaudited)**

	<b>Three months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Revenues:</b>		
Collaboration agreements	\$ 2,084	\$ 1,150
Research grants	681	272
Total revenues	2,765	1,422
<b>Operating expenses:</b>		
Research and development	8,646	5,430
General and administrative	2,927	1,999
Total operating expenses	11,573	7,429
Loss from operations	(8,808)	(6,007)
Interest and other income, net	836	648
Net loss	\$ (7,972)	\$ (5,359)
Basic and diluted net loss per share	\$ (0.20)	\$ (0.15)
Shares used in computing basic and diluted net loss per share	40,489	35,057

*See accompanying notes.*

**Table of Contents****SANGAMO BIOSCIENCES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands)****(Unaudited)**

	<b>Three months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Operating Activities:</b>		
Net loss	\$ (7,972)	\$ (5,359)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	115	50
Amortization of premium / discount on investments	(492)	(502)
Realized loss on investments		(2)
Stock-based compensation	1,718	543
Changes in operating assets and liabilities:		
Interest receivable	155	49
Accounts receivable	(404)	267
Prepaid expenses and other assets	(20)	75
Accounts payable and accrued liabilities	574	(196)
Accrued compensation and employee benefits	(457)	(290)
Deferred revenue	(1,610)	3
<b>Net cash used in operating activities</b>	<b>(8,393)</b>	<b>(5,362)</b>
<b>Investing Activities:</b>		
Purchases of investments	(27,302)	(18,753)
Maturities of investments	29,276	22,501
Proceeds from sales of investments	3,973	
Purchases of property and equipment	(366)	(126)
<b>Net cash provided by investing activities</b>	<b>5,581</b>	<b>3,622</b>
<b>Financing Activities:</b>		
Proceeds from issuance of common stock	479	68
<b>Net cash provided by financing activities</b>	<b>479</b>	<b>68</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(2,333)</b>	<b>(1,672)</b>
Cash and cash equivalents, beginning of period	12,275	12,702
<b>Cash and cash equivalents, end of period</b>	<b>\$ 9,942</b>	<b>\$ 11,030</b>

*See accompanying notes.*



**Table of Contents**

**SANGAMO BIOSCIENCES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

March 31, 2008

(Unaudited)

**NOTE 1-BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**BASIS OF PRESENTATION**

The accompanying unaudited condensed consolidated financial statements of Sangamo Biosciences, Inc. ( Sangamo or the Company ) have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission ( SEC ). Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. The condensed consolidated financial statements include the accounts of Sangamo and its wholly-owned subsidiary, Gendaq Limited, after elimination of all material intercompany balances and transactions. Operating results for the three months ended March 31, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. These financial statements should be read in conjunction with the financial statements and footnotes thereto for the year ended December 31, 2007, included in Sangamo s Form 10-K as filed with the SEC.

**USE OF ESTIMATES AND CLASSIFICATIONS**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

**FOREIGN CURRENCY TRANSLATION**

The Company records foreign currency transactions at the exchange rate prevailing at the date of the transaction. Monetary assets and liabilities denominated in foreign currency are translated into U.S. dollars at the exchange rates in effect at the balance sheet date. All currency translation adjustments arising from foreign currency transactions are recorded through statements of operations.

**REVENUE RECOGNITION**

In accordance with Staff Accounting Bulletin No. 104, Revenue Recognition, revenue from research activities made under strategic partnering agreements and Enabling Technology collaborations is recognized as the services are provided when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectibility is reasonably assured. Amounts received in advance under such agreements are deferred until the above criteria are met and the research services are performed. Sangamo s research grants are typically multi-year agreements and provide for the reimbursement of qualified expenses for research and development as defined under the terms of the grant agreement. Revenue under grant agreements is recognized when the related qualified research expenses are incurred. Grant reimbursements are received on a quarterly or monthly basis and are subject to the issuing agency s right of audit.

Milestone payments under research, partnering, or licensing agreements are recognized as revenue upon the achievement of mutually agreed upon milestones, provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement, and (ii) there are no remaining performance obligations associated with the milestone payment.

In accordance with Emerging Issues Task Force Issue No. 00-21, Revenue Arrangements with Multiple Deliverables, revenue arrangements entered into after June 15, 2003, that include multiple deliverables, are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration is allocated among the separate units of accounting based on their fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting.



**Table of Contents****RESEARCH AND DEVELOPMENT EXPENSES**

Research and development expenses consist of costs incurred for Company-sponsored as well as collaborative research and development activities. These costs include direct and research-related overhead expenses, which include salaries and other personnel-related expenses, stock-based compensation, pre-clinical and clinical studies, manufacturing costs, facility costs, laboratory supplies and depreciation of facilities and laboratory equipment, as well as the cost of funding research at universities and other research institutions, and are expensed as incurred. Costs to acquire technologies that are utilized in research and development and that have no alternative future use are expensed as incurred.

**STOCK-BASED COMPENSATION**

We account for employee stock-based compensation in accordance with FAS 123R. Under the provisions of FAS 123R, employee stock-based compensation is estimated at the date of grant based on the employee stock award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period in a manner similar to other forms of compensation paid to employees. The Black-Scholes option-pricing model requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. We primarily base our determination of expected volatility through our assessment of the historical volatility of our Common Stock. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures), and a comparison to relevant peer group data. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change.

Employee stock-based compensation expenses recognized in the three-month periods ended March 31, 2008 and 2007 were calculated based on awards ultimately expected to vest and have been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. As a result, stock-based compensation costs recognized in future periods may differ significantly from what we have recognized in the current period.

During 2007, we issued 100,000 restricted stock units under our 2004 Stock Incentive Plan at a grant date fair value of \$14.72. These restricted stock units will vest 25% after completion of one year of service and the balance will vest in equal monthly installments over the following thirty-six months of continued service. In accordance with FAS123R, the fair value of the restricted stock units was estimated based upon the closing sales price of the Company's common stock on the grant date.

The following table shows total stock-based compensation expenses included in the condensed consolidated statement of operations for the three-month periods ended March 31, 2008 and 2007 (in thousands):

	<b>Three months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
Costs and expenses:		
Research and development	\$ 856	\$ 347
General and administrative	862	196
Total stock-based compensation expense	\$ 1,718	\$ 543

As of March 31, 2008, total compensation costs related to nonvested stock options to be recognized in future periods were \$13.3 million and are expected to be expensed over a weighted average period of 2.98 years, and total compensation costs related to nonvested restricted stock units to be recognized in future periods were \$1.3 million and are expected to be expensed over a weighted average period of 3.67 years.

**Table of Contents****Valuation Assumptions**

The weighted average assumptions used for estimating the fair value of the employee stock options are as follows:

	Three months ended March 31,	
	2008	2007
Risk-free interest rate	2.46%	4.58%
Expected life of option	5.20 years	6.25 years
Expected dividend yield of stock	0.0%	0.0%
Expected volatility	0.67	0.93

The weighted average assumptions used for estimating the fair value of the purchase rights under the 2000 Employee Stock Purchase Plan are as follows:

	Three months ended March 31,	
	2008	2007
Risk-free interest rate	3.95-4.95%	3.60-5.1%
Expected life of option	0.5-2 years	0.5-2 yrs
Expected dividend yield of stock	0.0%	0.0%

**Stock Option Activity**

A summary of stock option activity is as follows:

	Shares Available for Grant of Options	Options Outstanding		Weighted Average Remaining Contractual Term (In Years)
		Number of Shares	Weighted- Average Exercise per Share Price	
Balance at January 1, 2008	3,191,668	4,750,973	\$ 8.01	7.15
Additional shares authorized	1,209,461			
Options granted	(64,500)	64,500	\$ 11.81	
Options exercised		(477,804)	\$ 0.99	
Options canceled	19,480	(19,480)	\$ 11.46	
Balance at March 31, 2008	4,356,109	4,318,189	\$ 8.83	7.59
Options exercisable at March 31, 2008		1,972,829	\$ 6.74	5.81

In accordance with our 2004 Stock Incentive Plan, the number of shares authorized for issuance automatically increases on the first trading day of the fiscal year by an amount equal to 3.0 percent of the total number of shares of our common stock outstanding on the last trading day of the preceding year, but in no event shall any such increase exceed 1.75 million shares per year.

There were no shares subject to the Company's right of repurchase as of March 31, 2008. The intrinsic value of options exercised was \$5.5 million and \$81,000 for the three months ended March 31, 2008 and 2007, respectively.

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

The weighted-average estimated fair value per share of options granted during the three months ended March 31, 2008 and 2007 was \$6.87 and \$5.45, respectively, based upon the assumptions in the Black-Scholes valuation model described above.

The weighted-average estimated fair value per share of employee purchase rights during the three months ended March 31, 2008 and 2007 was \$3.13 and \$2.17, respectively, based upon the assumptions in the Black-Scholes valuation model described above.

**Table of Contents**

The following table summarizes information with respect to stock options outstanding at March 31, 2008:

Range of Exercise Price	Options Outstanding	
	Number of Shares	Weighted Average Remaining Contractual Life (In Years)
\$ 0.05 \$3.97	467,691	5.71
\$ 3.99 \$4.92	507,430	7.13
\$ 4.93 \$5.66	432,054	6.70
\$ 5.75 \$6.69	204,250	6.12
\$ 6.82 \$6.82	450,000	8.70
\$ 6.88 \$7.73	474,814	8.51
\$ 8.00 \$13.40	285,200	4.75
\$13.98 \$13.98	961,250	9.70
\$14.00 \$15.03	470,000	7.43
\$15.23 \$38.00	65,000	3.17
	4,318,189	7.59

At March 31, 2008, the aggregate intrinsic value of the outstanding and exercisable options was \$12.3 million and \$8.2 million, respectively.

Sangamo did not grant any stock option to consultants during the three months ended March 31, 2008 and 2007.

**RECENT ACCOUNTING PRONOUNCEMENTS**

In September 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 157, Fair-Value Measurements ( SFAS 157 ) which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair-value measurements. The Company adopted SFAS 157 effective January 1, 2008 for all financial assets and liabilities and any other assets and liabilities that are recognized or disclosed at fair value on a recurring basis (see NOTE 5 FAIR VALUE MEASUREMENT). In accordance with FASB Staff Position 157-2, *Effective Date of FASB Statement No. 157* ( FSP 157-2 ), for nonfinancial assets and liabilities measured at fair value on a non-recurring basis, SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2008. The Company is currently reviewing the application of SFAS 157 for nonfinancial assets and liabilities measured at fair value on a non-recurring basis and has not yet determined how the adoption of SFAS 157 will impact its condensed consolidated financial statements.

In June 2007, the EITF ratified a consensus on EITF Issue No. 07-3 (EITF 07-3), *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and recognized as an expense in the period that the related goods are delivered or services performed. The Company has adopted EITF 07-3 effective January 1, 2008, and the adoption had no material impact on our consolidated financial position, results of operations and cash flows.

In November 2007, the Emerging Issues Task Force (EITF) ratified a consensus on EITF Issue No. 07-1 (EITF 07-1), *Accounting for Collaborative Arrangements*, which requires participants in a collaboration to make separate disclosures regarding the nature and purpose of an arrangement, their rights and obligations under the arrangement, the accounting policy for the arrangement and the income statement classification and amounts arising from the arrangement between participants for each period an income statement is presented. EITF 07-1 is effective for us beginning in the first quarter of fiscal year 2009. We are currently evaluating the impact of the provisions of EITF 07-1 on our financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

**Table of Contents****NOTE 2-BASIC AND DILUTED NET LOSS PER SHARE**

Basic earnings (loss) per share is calculated based on the weighted average number of shares of common stock outstanding during the period. There are potential dilutive shares of common stock resulting from the assumed exercise of outstanding stock options and equivalents.

Because Sangamo is in a net loss position, diluted earnings (loss) per share excludes the effects of common stock equivalents consisting of options, which are all antidilutive. Had Sangamo been in a net income position, diluted earnings per share would have included the shares used in the computation of basic net loss per share as well as an additional 1,688,629 shares and 2,387,216 shares for the three months ended 2008 and 2007, respectively, related to outstanding options.

**NOTE 3-COMPREHENSIVE LOSS**

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in stockholders' equity that are excluded from net loss, which includes unrealized gains and losses on available-for-sale securities. Comprehensive loss and its components are as follows (in thousands):

	Three months ended	
	March 31,	
	2008	2007
Net loss	\$ (7,972)	\$ (5,359)
Changes in unrealized gains and losses on securities available-for-sale	110	(2)
Comprehensive loss	\$ (7,862)	\$ (5,361)

**NOTE 4-MAJOR CUSTOMERS, PARTNERSHIPS AND STRATEGIC ALLIANCES****Agreement with Dow AgroSciences in Plant Agriculture**

On October 1, 2005, we entered into a Research License and Commercial Option Agreement with Dow AgroSciences LLC ( DAS ), a wholly owned indirect subsidiary of Dow Chemical Corporation. Under this agreement, we will provide DAS with access to our proprietary ZFP technology and the exclusive right to use our ZFP technology to modify the genomes or alter the nucleic acid or protein expression of plant cells, plants, or plant cell cultures. We have retained rights to use plants or plant-derived products to deliver ZFP TFs or ZFNs into human or animals for diagnostic, therapeutic, or prophylactic purposes. We have achieved several milestones in this collaboration.

Our agreement with DAS provides for an initial three-year research term during which time we are working together to validate and optimize the application of our ZFP technology to plants, plant cells and plant cell cultures. During the three-year research term, DAS has the option to obtain a commercial license to sell products incorporating or derived from plant cells generated using our ZFP technology, including agricultural crops, industrial products and plant-derived biopharmaceuticals. The option expires on September 30, 2008. This commercial license will be exclusive for all such products other than animal and human health products. In the event that DAS exercises this option, DAS may elect to extend the research program beyond the initial three-year term on a year-to-year basis.

Pursuant to the Research License and Commercial Option Agreement, DAS made an initial cash payment to us of \$7.5 million. In November 2005, the Company sold approximately 1.0 million shares of common stock to DAS at a price of \$3.85 per share, resulting in proceeds of \$3.9 million. In addition, DAS will provide \$6.0 million in research funding over the initial three-year research term and may make an additional payment of up to \$4.0 million in research milestone payments to us during this same period, depending on the success of the research program. In the event that DAS elects to extend the research program beyond the initial three-year term, DAS will provide additional research funding. If DAS exercises its option to obtain a commercial license, we will be entitled to full payment of the \$4.0 million in research milestones, a one-time exercise fee of \$6.0 million, minimum annual sublicensing payments totaling to up to \$25.3 million over 11 years, development and commercialization milestone payments for each product, and royalties on sales of products. Furthermore, DAS will have the right to sublicense our ZFP technology to third parties for use in plant cells, plants, or plant cell cultures, and we will be entitled to 25% of any cash consideration received by DAS under such sublicenses.





**Table of Contents**

We have agreed to supply DAS and its sublicensees with ZFP TFs and/or ZFNs for both research and commercial use over the three year period of the agreement. If DAS exercises its option to obtain a commercial license, DAS may request that we transfer, at DAS's expense, the ZFP manufacturing technology to DAS or to a mutually agreed-upon contract manufacturer.

The Research License and Commercial Option Agreement will terminate automatically if DAS fails to exercise its option for a commercial license by the end of the initial three-year research term or September 30, 2008. Following DAS's exercise of the option and payment of the exercise fee, DAS may terminate the agreement at any time. In addition, each party may terminate the agreement upon an uncured material breach of the other party. In the event of any termination of the agreement, all rights to use our ZFP technology will revert to us, and DAS will no longer be permitted to practice our ZFP technology or to develop or, except in limited circumstances, commercialize any products derived from our ZFP technology. Revenues related to the research license under the DAS agreement are being recognized ratably over the initial three-year research term of the agreement and were \$625,000 during both three month periods ended March 31, 2008 and 2007. Revenues attributable to collaborative research and development performed under the agreement were \$500,000 during both three month periods ended March 31, 2008 and 2007. Revenues attributable to the achievement of at-risk milestones were \$180,000 and \$0 during the three months ended March 31, 2008 and 2007, respectively. Related costs and expenses incurred under the agreement were \$500,000 during both three month periods ended March 31, 2008 and 2007.

**Agreement with Sigma-Aldrich Corporation in Laboratory Research Reagents**

In July 2007, we entered into a license agreement with Sigma-Aldrich Corporation (Sigma). Under the License Agreement, we are providing Sigma with access to our proprietary ZFP technology and the exclusive right to use the technology to develop and commercialize research reagents products and services in the research field, excluding certain agricultural research uses that Sangamo previously licensed to Dow AgroSciences LLC. Under the agreement, Sangamo and Sigma have agreed to conduct a three-year research program to develop laboratory research reagents using our ZFP technology. In addition, for three years we will assist Sigma in connection with Sigma's efforts to market and sell services employing our technology in the research field. We will transfer the ZFP manufacturing technology to Sigma or to a mutually agreed-upon contract manufacturer upon Sigma's request. Prior to the completion of this transfer, we will be responsible for supplying ZFPs for use by Sigma in performing services in the research field. Under the terms of the agreement, Sigma made an initial payment comprising an upfront license fee and the purchase of one million (1,000,000) shares of Sangamo's common stock under a separate stock purchase agreement, resulting in a total upfront payment to Sangamo of \$13.5 million. There were three components to the \$13.5 million we received: an equity investment by Sigma in Sangamo common stock valued at \$8.55 million, a \$3.95 million license fee, and \$1.0 million of research funding. Under the License Agreement, we may receive additional research funding of up to \$2.0 million, development milestone payments of up to \$5.0 million, and commercial milestone payments based on net sales of up to \$17.0 million, subject to the continuation of the agreement. During the term of the license agreement Sigma is obligated to pay to Sangamo minimum annual payments, a share of certain revenues received by Sigma from sublicensees, and royalty payments on the sale of licensed products and services. Sigma also has the right to sublicense the ZFP technology for research applications and we will receive 50% of any sublicensing revenues in the first two years and 25% of any sublicensing revenues thereafter. We retain the sole right to use and license our ZFP technology for GMP production purposes, for the production of materials used in or administered to humans, and for any other industrial commercial use. Revenues related to the research license under the Sigma agreement are being recognized ratably over the three-year research term of the agreement and were \$329,000 during the three months ended March 31, 2008. Revenues attributable to collaborative research and development performed under the Sigma agreement were \$250,000 during the three months ended March 31, 2008. Related costs and expenses incurred under the Sigma agreement were \$317,000 during the three months ended March 31, 2008.

**Enabling Technology Collaborations in Pharmaceutical Protein Production**

We have established several research collaborations in this area. In December 2004, we announced a research collaboration agreement with Pfizer to use our ZFP technology to develop enhanced cell lines for protein pharmaceutical production. The scope of this agreement was expanded in January 2006 and again in January 2007 and provided further research funding from Pfizer to develop additional cell lines for enhanced protein production. Under the terms of the agreement, Pfizer is funding research at Sangamo and Sangamo will provide our proprietary ZFP technology for Pfizer to assess its feasibility for use in mammalian cell-based protein production. We are generating novel cell lines and vector systems for enhanced protein production as well as novel technology for rapid creation of new production cell lines. Revenues attributable to collaborative research and development performed under the Pfizer agreement were \$0 and \$25,000 during the three months ended March 31, 2008 and 2007, respectively. Related research and development costs and expenses performed under the Pfizer agreement were \$36,000 and \$134,000 during the three months ended March 31, 2008 and 2007, respectively.

**Table of Contents**

In addition, in April 2007, we established a research and license agreement with Genentech, Inc. ( Genentech ). Under our agreement with Genentech, we are developing, ZFNs capable of making targeted modifications to the genome of Genentech cell lines to generate cell lines with novel characteristics for protein pharmaceutical production purposes. The agreement was expanded to include further ZFNs in February 2008. Genentech paid an upfront fee of \$400,000, will pay an ongoing technology access fee, and certain payments upon achievement of specified milestones relating to the research of ZFNs and the development and commercialization of products manufactured using a modified cell line created by our ZFN technology. Revenues attributable to collaborative research and development performed under the Genentech agreement were \$50,000 during the three months ended March 31, 2008. Revenues attributable to the achievement of milestones was \$150,000 during the three months ended March 31, 2008. Related research and development costs and expenses performed under the Genentech agreement were \$31,000 during the three months ended March 31, 2008.

**Funding from Research Foundations****The Juvenile Diabetes Research Foundation International**

On October 26, 2006, Sangamo announced a partnership with the Juvenile Diabetes Research Foundation International (JDRF) to provide financial support to one of Sangamo's Phase 2 human clinical studies of SB-509 (SB-509-601), a ZFP Therapeutic™ that is in development for the treatment of diabetic neuropathy. Under the agreement with JDRF and subject to its terms and conditions, including the Company's achievement of certain milestones associated with the Company's Phase 2 clinical trial of SB-509 for the treatment of mild to moderate diabetic neuropathy, JDRF will pay the Company an aggregate amount of up to \$3.0 million. After the first commercial launch of SB-509 in a major market, JDRF has the right to receive, subject to certain limitations, annual payments from Sangamo, until such time when the total amount paid to JDRF, including payments made on account of certain licensing arrangements, equals three times the amount received by us from JDRF.

Under the agreement, we are obligated to use commercially reasonable efforts to carry out the Phase 2 trial and, thereafter, to develop and commercialize, a product containing SB-509 for the treatment of diabetes and complications of diabetes. We are obligated to cover all costs of the Phase 2 trial that are not covered by JDRF's grant. If we fail to satisfy these obligations, JDRF may have the right, subject to certain limitations, to obtain an exclusive, sublicensable license, to the intellectual property generated by us in the course of the Phase 2 trial, to make and commercialize products containing SB-509 for the treatment of diabetes and complications of diabetes. If JDRF obtains such a license, it is obligated to pay us a percentage of its revenues from product sales and sublicensing arrangements. If JDRF fails to satisfy its obligations to develop and commercialize a product containing SB-509 under the Agreement, then their license rights will terminate and we will receive a non-exclusive, fully paid license, for any intellectual property developed during JDRF's use of the license, to research, develop and commercialize products containing SB-509 for the treatment of diabetes and complications of diabetes.

Through March 31, 2008, we have received \$2.5 million. Revenues attributable to research and development performed under the JDRF partnership were \$375,000 and \$0 during the three months ended March 31, 2008 and 2007, respectively. Related costs and expenses incurred were \$1.5 million and \$1.2 million during the three months ended March 31, 2008 and 2007, respectively.

**The Michael J. Fox Foundation**

On January 23, 2007, Sangamo announced a partnership with the Michael J. Fox Foundation (MJFF) to provide financial support of Sangamo's ZFP TFs™ to activate the expression of glial cell line-derived neurotrophic factor (GDNF) that has shown promise in preclinical testing to slow or stop the progression of Parkinson's disease. Under the agreement with MJFF and subject to its terms and conditions, MJFF will pay the Company \$950,000 over a period of two years. Through March 31, 2008, we have received \$679,000. Revenues attributable to research and development performed under the MJFF partnership were \$252,000 and \$50,000 during the three months ended March 31, 2008 and 2007, respectively. Related costs and expenses incurred under the MJFF partnership were \$253,000 and \$50,000 during the three months ended March 31, 2008 and 2007, respectively.

**NOTE 5-FAIR VALUE MEASUREMENT**

We adopted the measurement and disclosure requirements of FASB Statement No. 157 related to financial assets and liabilities effective January 1, 2008. There was no impact from the adoption of Statement No. 157 on the condensed consolidated financial statements. Statement No. 157 establishes a framework for measuring fair value and expands disclosure about fair value measurements. The statement requires fair value measurement be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;



**Table of Contents**

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The following table summarizes our financial instruments as of March 31, 2008 (in thousands):

	March 31, 2008			
	Fair Value Measurements			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Marketable securities:				
Commercial paper	\$ 35,385	\$	\$ 35,385	\$
Government agencies	11,036		11,036	
Asset backed securities	10,033		10,033	
Corporate notes	6,002		6,002	
Bank notes	1,012	1,012		
Total	\$ 63,468	\$ 1,012	\$ 62,456	\$

**NOTE 6-INCOME TAXES**

The Company adopted FASB Interpretation 48, Accounting for Uncertainty in Income Taxes ( FIN 48 ), on January 1, 2007. As a result of the implementation of FIN 48, the Company did not recognize any adjustment to the liability for uncertain tax positions and therefore did not record any adjustment to the beginning balance of retained earnings on the consolidated balance sheet. As of the date of adoption, the Company recorded a \$1.1 million reduction to deferred tax assets and the associated valuation allowance for unrecognized tax benefits. If the unrecognized tax benefits were recognized, there would be no impact on the effective tax rate.

We maintain deferred tax assets that reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These deferred tax assets include net operating loss carryforwards, research credits and capitalized research and development. The net deferred tax asset has been fully offset by a valuation allowance because of the Company's history of losses. Utilization of operating losses and credits may be subject to substantial annual limitation due to ownership change provisions of the Internal Revenue Code of 1986, as amended and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

**NOTE 7-SUBSEQUENT EVENTS**

On April 2, 2008, Sangamo entered into a License Agreement with Open Monoclonal Technology, Inc. ( OMT ), pursuant to which Sangamo will grant a royalty-bearing, non-exclusive, sublicensable worldwide license to OMT for the commercial use of a transgenic animal generated using Sangamo's ZFP technology.

In consideration of the license and rights granted to OMT, OMT will pay Sangamo an upfront license fee, payments upon the achievement of certain clinical development milestones, a share of payments received by OMT from sublicensees, and royalties on sales of any products developed using Sangamo's ZFP technology. For any given OMT Product, OMT has the right to buy out its future royalty payment obligations under the agreement by paying a lump sum fee to Sangamo.

---

**Table of Contents**

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations contains trend analysis, estimates and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, without limitation, statements containing the words believes, anticipates, expects, continue, and other words of similar import or the negative of those terms or expressions. Such forward-looking statements are subject to known and unknown risks, uncertainties, estimates and other factors that may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Actual results could differ materially from those set forth in such forward-looking statements as a result of, but not limited to, the Risk Factors described below. You should read the following discussion and analysis along with the financial statements and notes attached to those statements included elsewhere in this report and in our annual report on Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission on March 3, 2008.

**Overview**

We were incorporated in June 1995. From our inception through March 31, 2008, our activities related primarily to establishing and operating a biotechnology research and development organization and developing relationships with our corporate collaborators. Our scientific and business development endeavors currently focus on the engineering of novel zinc finger DNA-binding proteins (ZFPs) for the regulation and modification of genes. We have incurred net losses since inception and expect to incur losses in the future as we continue our research and development activities. To date, we have funded our operations primarily through the issuance of equity securities, borrowings, payments from research grants and from corporate collaborators and strategic partners. As of March 31, 2008, we had an accumulated deficit of \$157.7 million.

Our revenues have consisted primarily of revenues from our corporate partners for ZFP TFs and ZFNs, contractual payments from strategic partners for research programs and research milestones, and research grant funding. We expect revenues will continue to fluctuate from period to period and there can be no assurance that new collaborations or partner fundings will continue beyond their initial terms.

We have continued to place more emphasis on higher-value therapeutic product development and related strategic partnerships and less emphasis on our Enabling Technology collaborations. We believe this shift in emphasis has the potential to increase the return on investment to our stockholders by allocating capital resources to higher value, therapeutic product development activities. At the same time, it may reduce our revenues over the next several years and subject us to higher financial risk by increasing expenses associated with product development. We filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) and have initiated three Phase 2 clinical trials of a ZFP Therapeutic in patients with diabetic neuropathy. Development of novel therapeutic products is costly and is subject to a lengthy and uncertain regulatory process by the FDA. Our future products are gene-based therapeutics. Adverse events in both our own clinical program and other programs may have a negative impact on regulatory approval, the willingness of potential commercial partners to enter into agreements and the perception of the public.

Research and development expenses consist primarily of salaries and related personnel expenses, pre-clinical and clinical studies, laboratory supplies, stock-based compensation expenses, allocated facilities costs, subcontracted research expenses, and expenses for technology licenses. Research and development costs incurred in connection with collaborator-funded activities are expensed as incurred. Costs to acquire technologies that are utilized in research and development and that have no alternative future use are expensed as incurred. We believe that continued investment in research and development is critical to attaining our strategic objectives. We expect these expenses will increase significantly as we focus increasingly on development of ZFP Therapeutics. Additionally, in order to develop ZFP TFs and ZFNs as commercially relevant therapeutics, we expect to expend additional resources for expertise in the manufacturing, regulatory affairs and clinical research aspects of biotherapeutic development.

General and administrative expenses consist primarily of salaries and related personnel expenses for executive, finance and administrative personnel, professional fees, patent prosecution expenses, allocated facilities costs and other general corporate expenses. As we pursue commercial development of our therapeutic leads we expect the business aspects of the Company to become more complex. We may be required in the future to add personnel and incur additional costs related to the maturity of our business.

**Critical Accounting Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting



**Table of Contents**

period. Such estimates are described in Note 1, Basis of Presentation and Summary of Significant Accounting Policies to the Unaudited Notes to Condensed Consolidated Financial Statements. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources, and evaluate our estimates on an ongoing basis. Actual results could differ from those estimates under different assumptions or conditions.

**RESULTS OF OPERATIONS**

Three months ended March 31, 2008 and 2007

**Revenues**

	Three months ended March 31, (in thousands, except percentage values)			
	2008	2007	Change	%
Revenues:				
Collaboration agreements	\$ 2,084	\$ 1,150	\$ 934	81%
Research grants	681	272	409	150%
Total revenues	\$ 2,765	\$ 1,422	\$ 1,343	94%

Total revenues consist of revenues from collaboration agreements, strategic partnerships and research grants. Revenues from our corporate collaboration and strategic partnering agreements were \$2.1 million for the three months ended March 31, 2008, compared to \$1.2 million in the corresponding period in 2007. The increase in collaboration agreements was principally attributable to revenues of \$579,000 in connection with our laboratory research reagents license agreement with Sigma-Aldrich Corporation ( *Sigma* ), revenues of \$200,000 in connection with our research and license agreement with Genentech, Inc. ( *Genentech* ) and increased revenues of \$180,000 in connection with our research license and commercial option agreement with Dow AgroSciences LLC ( *DAS* ), partially offset by decreased revenues of \$25,000 from Pfizer. Research grant revenues were \$681,000 for the three months ended March 31, 2008, compared to \$272,000 in the corresponding period in 2007. The increase in research grant revenues was principally due to revenues of \$375,000 in connection with our grant from the Juvenile Diabetes Research Foundation ( *JDRF* ) and increased revenues of \$200,000 related to the Michael J. Fox Foundation ( *MJFF* ) grant, partially offset by decreased revenues of \$200,000 in connection with our Advanced Technical Program grant awarded by the National Institute of Standards and Technology. We anticipate continued revenues from collaboration agreements, and we have applied for, and plan to continue to apply for research grants in the future to support the development of applications of our technology platform. Although we have negotiated collaboration agreements and received research grants in the past, we cannot assure that these efforts will be successful in the future.

**Operating Expenses**

	Three months ended March 31, (in thousands, except percentage values)			
	2008	2007	Change	%
Operating Expenses:				
Research and development	\$ 8,646	\$ 5,430	\$ 3,216	59%
General and administrative	2,927	1,999	928	46%
Total expenses	\$ 11,573	\$ 7,429	\$ 4,144	56%

**Research and development**

Research and development expenses consist primarily of salaries and related personnel expenses, stock-based compensation expense, laboratory supplies, pre-clinical and clinical studies, manufacturing costs, allocated facilities costs, subcontracted research expenses and expenses for trademark registration and technology licenses. We expect to continue to devote substantial resources to research and development in the future and expect research and development expenses to increase in the next several years if we are successful in advancing our ZFP Therapeutic

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

product candidates into clinical trials. To the extent we collaborate with others with respect to clinical trials, increases in research and development expenses may be reduced or avoided.

Research and development expenses were \$8.6 million for the three months ended March 31, 2008, compared to \$5.4 million in the corresponding period in 2007. The increase in research and development expenses was primarily attributable to increased pre-clinical and clinical studies and manufacturing expenses of \$1.7 million, primarily associated with our diabetic neuropathy program, and



**Table of Contents**

increased salaries and personnel related expenses of \$781,000, including stock-based compensation expenses of \$511,000. The increase in stock-based compensation was due to increased grant activity, higher Black-Scholes value per share and a lower estimated forfeiture rate which the Company believes is more representative of its historical experience. Consulting expenses increased by \$321,000 primarily in support of our diabetic neuropathy program, facility-related expenses increased by \$228,000 primarily due to the Company leasing additional space and increased headcount, and licensing expenses increased by \$109,000 primarily due to increased royalty payments.

**General and administrative**

General and administrative expenses consist primarily of salaries and related personnel expenses for executive, finance and administrative personnel, stock-based compensation expenses, professional fees, allocated facilities costs, expenses for patent prosecution and other general corporate expenses. As we pursue commercial development of our therapeutic leads, we expect the business aspects of the Company to become more complex. We may be required in the future to add personnel and incur additional costs related to the maturity of our business.

General and administrative expenses were \$2.9 million for the three months ended March 31, 2008, compared to \$2.0 million in the corresponding period in 2007. This increase is attributable to increased salaries and personnel related expenses of \$901,000, including stock-based compensation expenses of \$666,000. The increase in stock-based compensation was due to increased grant activity, higher Black-Scholes value per share and a lower estimated forfeiture rate as noted above.

**Interest and Other Income, net**

	Three months ended March 31, (in thousands, except percentage values)			
	2008	2007	Change	%
Interest and other income, net	\$ 836	\$ 648	\$ 188	29%

Interest and other income, net, was \$836,000 for the three months ended March 31, 2008, compared to \$648,000 in the corresponding period in 2007. The increase was primarily related to higher average investment balances during the quarter ended March 31, 2008.

**Liquidity and Capital Resources**

Since inception, we have financed our operations primarily through the sale of equity securities, payments from corporate collaborators, research grants and financing activities such as a bank line of credit. As of March 31, 2008, we had cash, cash equivalents, short-term investments and interest receivable totaling \$73.6 million.

Net cash used in operating activities was \$8.4 million for the three months ended March 31, 2008. Net cash used in operating activities consisted of the net loss for the three-month period of \$8.0 million, a net change of \$1.8 million in operating assets and liabilities, partially offset by non-cash charges of \$1.3 million. The net decrease in operating liabilities of \$1.5 million was principally comprised of decreases in deferred revenues of \$1.6 million and accrued compensation and employee benefits of \$457,000, partially offset by an increase of \$574,000 in accounts payable and accrued liabilities. The net increase in operating assets of \$269,000 was principally comprised of increased accounts receivable balances of \$404,000, partially offset by decreased interest receivable balances of \$155,000. The non-cash charges included \$1.7 million related to stock-based compensation and \$115,000 related to depreciation and amortization, partially offset by amortization of premium / discount on investments of \$492,000. Net cash used in operating activities was \$5.4 million for the three months ended March 31, 2007. Net cash used in operating activities consisted primarily of the net loss for the three month period of \$5.4 million and a net change of \$92,000 in operating assets and liabilities, partially offset by non-cash charges of \$89,000. The net decrease in operating liabilities of \$483,000 was principally comprised of decreases in accrued compensation and employee benefits of \$290,000 and accounts payable and accrued liabilities of \$196,000. The net decrease in operating assets of \$391,000 was principally comprised of decreased accounts receivable balances of \$267,000, prepaid expenses and other assets of \$75,000 and interest receivable of \$49,000. The non-cash charges included \$543,000 related to stock-based compensation and \$50,000 related to depreciation and amortization, partially offset by amortization of premium / discount on investments of \$502,000.

Net cash provided by investing activities was \$5.6 million for the three months ended March 31, 2008 and was comprised of cash proceeds associated with maturities of investments of \$29.3 million and proceeds from sales of investments of \$4.0 million, partially offset by cash used to purchase investments and fixed assets of \$27.3 million and \$366,000, respectively. Net cash provided by investing activities was \$3.6 million for the three months ended March 31, 2007 and was comprised of cash proceeds associated with maturities of investments of \$22.5 million, partially offset by cash used to purchase investments and fixed assets of \$18.8 million and \$126,000, respectively.



## **Table of Contents**

Net cash provided by financing activities for the three-month periods ended March 31, 2008 and 2007 was \$479,000 and \$68,000, respectively. Proceeds from both years were solely related to proceeds from the issuance of common stock related to stock option exercises.

While we expect our rate of cash usage to increase in the future, in particular to support our product development endeavors, we believe that the available cash resources, funds received from corporate collaborators, strategic partners and research grants will be sufficient to finance our operations through 2009. We may need to raise additional capital to fund our ZFP Therapeutic development activities. Additional capital may not be available in terms acceptable to us, or at all. If adequate funds are not available, our business, and our ability to develop our technology and our ZFP Therapeutic products, would be harmed.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk for changes in interest rates relates primarily to our cash equivalents and investments. The investments are available-for-sale. We do not use derivative financial instruments in our investment portfolio. We attempt to ensure the safety and preservation of our invested funds by limiting default and market risks. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. We select investments that maximize interest income to the extent possible within these guidelines. We satisfy liquidity requirements by investing excess cash in securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying our investments among a variety of high credit-quality issuers. We mitigate default risk by investing in only investment-grade securities. The portfolio includes marketable securities with active secondary or resale markets to ensure portfolio liquidity. All investments have a fixed interest rate and are carried at market value, which approximates cost.

Our market risks at March 31, 2008 have not changed materially from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2007 on file with the Securities and Exchange Commission.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **(a) Evaluation of Disclosure Controls and Procedures**

The Company's management, with the participation of the Company's Chief Executive Officer and Principal Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Principal Financial Officer concluded that the Company's disclosure controls and procedures as of the end of the period covered by this report were functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Principal Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

#### **(b) Change in Internal Control over Financial Reporting**

No change in the Company's internal control over financial reporting occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

---

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

We are not party to any material pending legal proceedings, other than routine litigation incidental to our business.

**ITEM 1A. RISKS FACTORS**

This Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of Sangamo, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our revenues, expenses, net loss and loss per share.

***ZFP Therapeutics have undergone limited testing in humans and our ZFP Therapeutics may fail safety studies in clinical trials.***

We have initiated and completed a Phase 1 study and initiated several Phase 2 clinical trial in our lead ZFP Therapeutic program. We have completed enrollment and treatment of the patients in the first of these trials of SB-509 for diabetic neuropathy and thus far have not observed any serious drug-related adverse events. However if our lead ZFP Therapeutic fails one of its initial safety studies, it could reduce our ability to attract new investors and corporate partners. In January 2005, we filed an IND with the FDA for SB-509, a ZFP TF activator of VEGF-A, for the treatment of mild to moderate diabetic neuropathy. We have completed enrollment and treatment of a Phase 1, single blind, single dose, dose-escalation trial to measure the laboratory and clinical safety of SB-509. We have completed enrollment of a repeat-dosing Phase 2 clinical trial (SB-509-601) and have 2 other related Phase 2 trials ongoing for this indication (SB-509-701 and SB-509-703). Some trial subjects have received more than one dose of SB-509 during the course of these Phase 2 studies. In addition, Phase 1 clinical trials of an identical ZFP TF has been carried out in subjects with peripheral artery disease. These early studies of a ZFP Therapeutic are a highly visible test of our ZFP Therapeutic approach. Since we have increased our focus on ZFP Therapeutic research and development, investors will increasingly assess the value of our technology based on the continued progress of ZFP Therapeutic products into and through clinical trials. If the initial safety study of our lead therapeutic was halted due to safety concerns, this would negatively affect our operations and the value of our stock.

***The results of early Phase 1 trials are based on a small number of patients over a short period of time, and our progress may not be indicative of results in a large number of patients or of long-term efficacy.***

The results in early phases of clinical testing are based upon limited numbers of patients and a limited follow-up period. Typically, our Phase 1 clinical trials for indications of safety enroll less than 50 patients. The initial results from the Phase 1 clinical trial of our ZFP Therapeutic, SB-509 product, became available in the first half of 2006 and more were presented in June and November of 2007. The primary end point of the trial was clinical and laboratory safety, however we collected some preliminary efficacy data that showed trends of clinical improvement in some subjects. Our first Phase 2 clinical trial (SB-509-601) for safety and efficacy has enrolled 110 patients. Actual results with more data points may not confirm favorable results from earlier stage trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in earlier stage clinical trials. If a larger population of patients does not experience positive results, or if these results are reproducible, our products may not receive approval from the FDA. Failure to demonstrate the safety and effectiveness of our ZFP Therapeutic products in larger patient populations could have a material adverse effect on our business that would cause our stock price to decline significantly.

***We have limited experience in conducting clinical trials.***

Our ZFP Therapeutics may fail to show the desired safety and efficacy in initial clinical trials. We have completed a Phase 1 trial and initiated several Phase 2 clinical trials, completing enrollment on one of these studies. However, the FDA will require additional clinical testing which involves significantly greater resources, commitments and expertise that may require us to enter into a collaborative relationship with a pharmaceutical company that could assume responsibility for late-stage development and commercialization.

## **Table of Contents**

*We may not be able to find acceptable patients or may experience delays in enrolling patients for our clinical trials.*

We may be competing for suitable patients with other clinical trials. We or the FDA may suspend our clinical trials at any time if either believes that we are exposing the subjects participating in these trials to unacceptable health risks. The FDA or institutional review boards and/or institutional biosafety committees at the medical institutions and healthcare facilities where we sponsor clinical trials may suspend any trial indefinitely if they find deficiencies in the conduct of these trials. The FDA and institutional review boards may also require large numbers of patients, and the FDA may require that we repeat a clinical trial.

*Our potential therapeutic products are subject to a lengthy and uncertain regulatory process, and we may encounter unanticipated toxicity or adverse events or fail to demonstrate efficacy, causing us to delay, suspend or terminate the development of a ZFP Therapeutic. If these potential products are not approved, we will not be able to commercialize those products.*

The FDA must approve any human therapeutic product before it can be marketed in the United States. The process for receiving regulatory approval is long and uncertain, and a potential product may not withstand the rigors of testing under the regulatory approval processes.

Before commencing clinical trials in humans, we must submit an Investigational New Drug (IND) application to the FDA. The FDA has 30 days to comment on the IND. If the FDA does not comment on the IND, we or our commercial partner may begin clinical trials.

Clinical trials are subject to oversight by institutional review boards and the FDA. In addition, our proposed clinical studies require review from the Recombinant DNA Advisory Committee, or RAC, which is the advisory board to the National Institutes of Health, or NIH, focusing on clinical trials involving gene transfer. We will typically submit a proposed clinical protocol and other product-related information to the RAC three to six months prior to the expected IND filing date.

Clinical trials:

must be conducted in conformance with the FDA's good clinical practices ICH guidelines and other applicable regulations;

must meet requirements for institutional review board (IRB) oversight;

must follow Institutional Biosafety Committee (IBC) and NIH RAC guidelines where applicable;

must meet requirements for informed consent;

are subject to continuing FDA oversight;

may require large numbers of test subjects; and

may be suspended by a commercial partner, the FDA, or us at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in the IND or the conduct of these trials.

While we have stated our intention to file additional IND applications during the next several years, this is only a statement of intent, and we may not be able to do so because the associated product candidates may not meet the necessary preclinical requirements. In addition, there can be no assurance that, once filed, an IND application will result in the actual initiation of clinical trials.

*As we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates.*

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

We cannot commercialize any of our ZFP Therapeutics to generate revenue until the appropriate regulatory authorities have reviewed and approved the applications for the product candidates. We cannot assure that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate that we or our collaborators develop.

---

## **Table of Contents**

Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Regulatory approval processes outside the United States include all of the risks associated with the FDA approval process. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

***If we establish drug development collaborations, our collaborators may control aspects of our clinical trials, which could result in delays and other obstacles in the commercialization of our proposed products.***

For some programs we may be dependent on third party collaborators to design and conduct our clinical trials. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate. In addition, if any of these collaborative partners withdraw support for our programs or proposed products or otherwise impair their development, our business could be negatively affected.

***We have increased the focus of our research and development programs on human therapeutics, which will increase operating expenditures and the uncertainty of our business.***

We have significantly increased the emphasis and focus of our research and development activities on ZFP Therapeutics and have fewer resources invested in our Enabling Technology programs. In the short term, this change may reduce our revenues and increase operating expenditures due to larger financial outlays to fund preclinical studies, manufacturing, and clinical research. The focus on ZFP Therapeutics will also increase the visibility of our lead therapeutic programs and the potential impact on the stock price of news releases relating to these programs.

***We are conducting proprietary research to discover ZFP Therapeutic product candidates. These programs increase our financial risk of product failure, may significantly increase our research expenditures, and may involve conflicts with future collaborators and strategic partners.***

Our proprietary research programs consist of research which is funded solely by the Company and where the Company retains exclusive rights to therapeutic products generated by the research. This is in contrast to certain of our research programs that may be funded by corporate partners and in which we may share rights to any resulting products. We have conducted proprietary research since inception. However, in the past several years, our strategy has shifted toward placing greater emphasis on proprietary research and therapeutic development and we expect this trend will continue in 2008 as we continue to prosecute our Phase 2 clinical trials and bring new ZFP Therapeutics into clinical trials. Conducting proprietary research programs may not generate corresponding revenue and may create conflicts with our collaborators or strategic partners over rights to our intellectual property with respect to our proprietary research activities. Any conflict with our collaborators or strategic partners could reduce our ability to enter into future collaborations or strategic partnering agreements and negatively impact our relationship with existing collaborators and strategic partners which could reduce our revenue and delay or terminate our product development. The implementation of this strategy will involve substantially greater business risks, the expenditure of significantly greater funds than our historic research activities and will require substantial commitments of time from our management and staff.

***Commercialization of our technologies will depend, in part, on strategic partnering with other companies. If we are not able to find strategic partners in the future or our strategic partners do not diligently pursue product development efforts, we may not be able to develop our technologies or products, which could slow our growth and decrease the value of our stock.***

We expect to rely, to some extent, on our strategic partners to provide funding in support of our research and to perform independent research and preclinical and clinical testing. Our technology is broad based, and we do not currently possess the resources necessary to fully develop and commercialize potential products that may result from our technologies or the resources or capabilities to complete the lengthy marketing approval processes that may be required for the products. Therefore, we plan to rely on strategic partnerships to help us develop and commercialize ZFP Therapeutic products. If we are unable to find strategic partners or if the partners we find are unable or unwilling to advance our programs, or if they do not diligently pursue product approval, this may slow our progress and defer our revenues. Our partners may sublicense or abandon development programs or we may have disagreements with our partners, which would cause associated product development to slow or cease. There can be no assurance that we will be able to establish strategic collaborations for ZFP Therapeutic product development. We may require significant time to secure collaborations or

## **Table of Contents**

strategic partners because we need to effectively market the benefits of our technology to these future collaborators and strategic partners, which use the time and efforts of research and development personnel and our management. Further, each collaboration or strategic partnering arrangement will involve the negotiation of terms that may be unique to each collaborator or strategic partner. These business development efforts may not result in a collaboration or strategic partnership.

The loss of any future strategic partnering agreements would not only delay or terminate the potential development or commercialization of products we may derive from our technologies, but it may also delay or terminate our ability to test ZFP therapeutic candidates for specific genes. If any strategic partner fails to conduct the collaborative activities successfully and in a timely manner, the preclinical or clinical development or commercialization of the affected product candidates or research programs could be delayed or terminated.

Under typical strategic partnering agreements we would expect to receive revenue for the research and development of a ZFP Therapeutic product and based on achievement of specific milestones. Achieving these milestones will depend, in part, on the efforts of our strategic partner as well as our own. If we, or any strategic partner, fail to meet specific milestones, then the strategic partnership may be terminated, which could decrease our revenues.

***Our gene regulation and gene modification technology is relatively new, and if we are unable to use this technology in all our intended applications, it would limit our revenue opportunities.***

Our technology involves a relatively new approach to gene regulation and gene modification. Although we have generated ZFPs for thousands of gene sequences, we have not created ZFPs for all gene sequences and may not be able to do so, which could limit the usefulness of our technology. In addition, while we have demonstrated the function of engineered ZFP TFs in mammalian cell culture, yeast, insects, plants, and animals, we have not yet definitively done so in humans, and the failure to do so could restrict our ability to develop commercially viable products. If we, and our collaborators or strategic partners, are unable to extend our results to new commercially important genes, experimental animal models, and human clinical studies, we may be unable to use our technology in all its intended applications. Also, delivery of ZFP TFs and ZFNs into cells and organisms, including humans, in these and other environments is limited by a number of technical hurdles, which we may be unable to surmount. This is a particular challenge for therapeutic applications of our technology that will require the use of gene transfer systems that may not be effective for the delivery of our ZFP TFs or ZFNs in a particular therapeutic application.

The expected value and utility of our ZFP TFs and ZFNs is in part based on our belief that the targeted or specific regulation of gene expression and targeted gene modification may enable us to develop a new therapeutic approach as well as to help scientists better understand the role of genes in disease, to aid their efforts in drug discovery and development. We also believe that the regulation of gene expression and targeted gene addition will have utility in agricultural applications. There is only a limited understanding of the role of specific genes in all these fields. Life sciences companies have developed or commercialized only a few products in any of these fields based on results from genomic research or the ability to regulate gene expression. We, our collaborators, or our strategic partners, may not be able to use our technology to identify and validate drug targets or to develop commercial products in the intended markets.

***We may be unable to license gene transfer technologies that we may need to commercialize our ZFP TF technology.***

In order to regulate or modify a gene in a cell, the ZFP TF or ZFN must be efficiently delivered to the cell. We have licensed certain gene transfer technologies for use with our Enabling Technologies, which are ZFP TFs and ZFNs used in pharmaceutical discovery research and protein production. We are evaluating these systems and other technologies that may need to be used in the delivery of ZFP TFs or ZFNs into cells for in vitro and in vivo applications, including ZFP Therapeutics. However, we may not be able to license the gene transfer technologies required to develop and commercialize our ZFP Therapeutics. We have not developed our own gene transfer technologies, and we rely on our ability to enter into license agreements to provide us with rights to the necessary gene transfer technology. The inability to obtain a license to use gene transfer technologies with entities which own such technology on reasonable commercial terms, if at all, could delay or prevent the preclinical evaluation, clinical testing, and/or commercialization of our therapeutic product candidates.

***We do not currently have the infrastructure or capability to manufacture therapeutic products on a commercial scale.***

In order for us to commercialize these products directly, we would need to develop, or obtain through outsourcing arrangements, the capability to execute all of these functions. If we are unable to develop or otherwise obtain the requisite preclinical, clinical,



## **Table of Contents**

regulatory, manufacturing, marketing, and sales capabilities, we would be unable to directly commercialize our therapeutics products which would limit our future growth.

*Even if our technology proves to be effective, it still may not lead to commercially viable products.*

Even if our collaborators or strategic partners are successful in using our ZFP technology in drug discovery, protein production, therapeutic development, or plant agriculture, they may not be able to commercialize the resulting products or may decide to use other methods competitive with our technology. To date, no company has received marketing approval or has developed or commercialized any therapeutic or agricultural products based on our technology. Should our technology fail to provide safe, effective, useful, or commercially viable approaches to the discovery and development of these products, this would significantly limit our business and future growth and would adversely affect our value.

*Even if our product development efforts are successful and even if the requisite regulatory approvals are obtained, our ZFP Therapeutics may not gain market acceptance among physicians, patients, healthcare payers and the medical community.*

A number of additional factors may limit the market acceptance of products including the following:

rate of adoption by healthcare practitioners;

rate of a product's acceptance by the target population;

timing of market entry relative to competitive products;

availability of alternative therapies;

price of our product relative to alternative therapies;

availability of third-party reimbursement;

extent of marketing efforts by us and third-party distributors or agents retained by us; and

side effects or unfavorable publicity concerning our products or similar products.

*Adverse events in the field of gene therapy may negatively impact regulatory approval or public perception of our potential products.*

Our potential therapeutic products are delivered to patients as gene-based drugs, or gene therapy. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy is unsafe, and, consequently, our products may not gain the acceptance of the public or the medical community. Negative public reaction to gene therapy in general could result in greater government regulation and stricter labeling requirements of gene therapy products, including any of our products, and could cause a decrease in the demand for any products we may develop.

*Our stock price is also influenced by public perception of gene therapy and government regulation of potential products.*

Reports of serious adverse events in a retroviral gene transfer trial for infants with X-linked severe combined immunodeficiency (X-linked SCID) in France and subsequent FDA actions putting related trials on hold in the United States had a significant negative impact on the public

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

perception and stock price of certain companies involved in gene therapy. Stock prices of these companies declined whether or not the specific company was involved with retroviral gene transfer for the treatment of infants with X-linked SCID, or whether the specific company's clinical trials were placed on hold in connection with these events. Other potential adverse events in the field of gene therapy may occur in the future that could result in greater governmental regulation of our potential products and potential regulatory delays relating to the testing or approval of our potential products

## Table of Contents

*We are at the development phase of operations and may not succeed or become profitable.*

We began operations in 1995 and are in the early phases of ZFP Therapeutic product development. We have incurred significant losses and our net losses for the past three fiscal years ended 2007, 2006 and 2005 were \$21.5 million, \$17.9 million and \$13.3 million, respectively. To date, our revenues have been generated from strategic partners, Enabling Technology collaborations, and federal government and research foundation grants. Since 2005, we have placed significant emphasis on higher-value therapeutic product development and related strategic partnerships. This shift in emphasis has the potential to increase the return on investment to our stockholders by allocating capital resources to higher value, therapeutic product development activities. At the same time, it increases our financial risk by increasing expenses associated with product development. In addition, the preclinical or clinical failure of any single product, such as our Phase 2 clinical trials of SB-509, may have a significant effect on the actual or perceived value of our shares. Our business is subject to all of the risks inherent in the development of a new technology, which included the need to:

attract and retain qualified scientific and technical staff and management, particularly scientific staff with expertise to develop our early-stage technology into therapeutic products;

obtain sufficient capital to support the expense of developing our technology platform and developing, testing, and commercializing products;

develop a market for our products;

successfully transition from a company with a research focus to a company capable of supporting commercial activities; and

attract and enter into research collaborations with research and academic institutions and scientists.

***If our competitors develop, acquire, or market technologies or products that are more effective than ours, this would reduce or eliminate our commercial opportunity.***

Any products that we or our collaborators or strategic partners develop by using our ZFP technology platform will enter into highly competitive markets. Even if we are able to generate ZFP Therapeutics that are safe and effective for their intended use, competing technologies may prove to be more effective or less expensive, which, to the extent these competing technologies achieve market acceptance, will limit our revenue opportunities. In some cases, competing technologies have proven to be satisfactorily effective and less expensive, as has been the case with technologies competitive with our Enabling Technology. The effectiveness of these competing products has reduced the revenues generated by our Enabling Technology. Competing technologies may include other methods of regulating gene expression or modifying genes. ZFP TFs and ZFNs have broad application in the life sciences and compete with a broad array of new technologies and approaches being applied to genetic research by many companies. Competing proprietary technologies with our product development focus include:

For ZFP Therapeutics:

small molecule drugs;

monoclonal antibodies;

recombinant proteins;

gene therapy/cDNAs;

antisense; and

siRNA approaches

For our Enabling Technology Applications:

For protein production: gene amplification, meganucleases, insulator technology, mini-chromosomes

For target validation: antisense, siRNA; and

For plant agriculture: recombination approaches, mutagenesis approaches, meganucleases, mini-chromosomes;

In addition to possessing competing technologies, our competitors include pharmaceutical and biotechnology companies with:

substantially greater capital resources than ours;

larger research and development staffs and facilities than ours; and

---

**Table of Contents**

greater experience in product development and in obtaining regulatory approvals and patent protection;

These organizations also compete with us to:

attract qualified personnel;

attract parties for acquisitions, joint ventures or other collaborations; and

license the proprietary technologies of academic and research institutions that are competitive with our technology, which may preclude us from pursuing similar opportunities.

Accordingly, our competitors may succeed in obtaining patent protection or commercializing products before us. In addition, any products that we develop may compete with existing products or services that are well established in the marketplace.

***Our collaborators or strategic partners may decide to adopt alternative technologies or may be unable to develop commercially viable products with our technology, which would negatively impact our revenues and our strategy to develop these products.***

Our collaborators or strategic partners may adopt alternative technologies, which could decrease the marketability of ZFP technology. Additionally, because many of our collaborators or strategic partners are likely to be working on more than one development project, they could choose to shift their resources to projects other than those they are working on with us. If they do so, this would delay our ability to test our technology and would delay or terminate the development of potential products based on our ZFP technology. Further, our collaborators and strategic partners may elect not to develop products arising out of our collaborative and strategic partnering arrangements or to devote sufficient resources to the development, manufacturing, marketing, or sale of these products. If any of these events occur, we may not be able to develop our technologies or commercialize our products.

***We anticipate continuing to incur operating losses for the next several years. If material losses continue for a significant period, we may be unable to continue our operations.***

We have generated operating losses since we began operations in 1995. The extent of our future losses and the timing of profitability are uncertain, and we expect to incur losses for the foreseeable future. We have been engaged in developing our ZFP TF technology since inception, which has and will continue to require significant research and development expenditures. In July 2007, we completed a registered direct offering to institutional investors for a total of 3,278,689 shares of common stock, at a price of \$9.15 per share, resulting in net proceeds to us of \$28.0 million. Also in July 2007, we entered into a license agreement and a related stock purchase agreement with Sigma-Aldrich Corporation (Sigma) under which we sold to Sigma 1.0 million shares of Sangamo's common stock valued at \$8.55 million. In June 2006, in an underwritten public offering and pursuant to an effective registration statement, we sold 3,100,000 shares of common stock at a public offering price of \$6.75 per share, resulting in net proceeds of approximately \$20.2 million. In November 2005, we completed a registered direct offering to institutional and strategic investors for a total of 5,080,000 shares of common stock at a price of \$3.85 per share to the investors, resulting in net proceeds to Sangamo of approximately \$18.2 million. To date, we have generated all other revenue from strategic partnering agreements, Enabling Technology collaborations, federal government research grants and grants awarded by research foundations. As of March 31, 2008, we had an accumulated deficit of approximately \$157.7 million. We expect to incur losses for the foreseeable future. These losses will increase as we expand and extend our research and development activities into human therapeutic product development. If the time required to generate significant product revenues and achieve profitability is longer than we currently anticipate or if we are unable to generate liquidity through equity financing, we may not be able to sustain our operations.

***We may be unable to raise additional capital, which would harm our ability to develop our technology and products.***

We have incurred significant operating losses and negative operating cash flows since inception and have not achieved profitability. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure and research and ZFP Therapeutic product development activities. While we believe our financial resources will be adequate to sustain our current operations at least through 2009, we may seek additional sources of capital through equity or debt financing. In addition, as we focus our efforts on proprietary human therapeutics, we will need to seek FDA approval of potential products, a process that could cost in excess of \$100 million per product. We cannot be certain that we will be able to obtain financing on terms acceptable to us, or at all. If adequate funds are not available, our business

and our ability to develop our technology and ZFP Therapeutic products would be harmed.

## **Table of Contents**

*Our stock price has been volatile and may continue to be volatile, which could result in substantial losses for investors.*

During the quarter ended March 31, 2008, our common stock price ranged from a low of \$8.83 to high of \$13.37. During the past two years, our common stock price has fluctuated significantly, ranging from a low of \$6.22 to a high of \$19.08 during the year ended December 31, 2007, and a low of \$4.10 to a high of \$8.00 during the year ended December 31, 2006. Volatility in our common stock could cause stockholders to incur substantial losses. An active public market for our common stock may not be sustained, and the market price of our common stock may continue to be highly volatile. The market price of our common stock has fluctuated significantly in response to the following factors, some of which are beyond our control:

announcements by us or future partners providing updates on the progress or development status of ZFP Therapeutics;

data from clinical trials;

changes in market valuations of similar companies;

deviations in our results of operations from the guidance given by us or estimates of securities analysts;

announcements by us or our competitors of new or enhanced products, technologies or services or significant contracts, acquisitions, strategic relationships, joint ventures or capital commitments;

regulatory developments;

additions or departures of key personnel;

future sales of our common stock or other securities by the Company, management or directors, liquidation of institutional funds that comprised large holdings of Sangamo stock; and

decreases in our cash balances.

*Our common stock is relatively thinly traded, which means large transactions in our common stock may be difficult to conduct in a short time frame.*

We have a relatively low volume of daily trades in our common stock on the Nasdaq Global Market. For example, the average daily trading volume in our common stock on the Nasdaq Global Market over the ten-day trading period prior to May 2, 2008 was approximately 361,930 shares per day. Any large transactions in our common stock may be difficult to conduct and may cause significant fluctuations in the price of our common stock.

*Because it is difficult and costly to protect our proprietary rights, and third parties have filed patent applications that are similar to ours, we cannot ensure the proprietary protection of our technologies and products.*

Our commercial success will depend in part on obtaining patent protection of our technology and successfully defending any of our patents that may be challenged. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and can involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict the breadth of claims allowed in patents we own or license.

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

We are a party to various license agreements that give us rights under specified patents and patent applications. Our current licenses, as our future licenses frequently will, contain performance obligations. If we fail to meet those obligations, the licenses could be terminated. If we are unable to continue to license these technologies on commercially reasonable terms, or at all, we may be forced to delay or terminate our product development and research activities.

With respect to our present and any future sublicenses, since our rights derive from those granted to our sublicensor, we are subject to the risk that our sublicensor may fail to perform its obligations under the master license or fail to inform us of useful improvements in, or additions to, the underlying intellectual property owned by the original licensor.

We are unable to exercise the same degree of control over intellectual property that we license from third parties as we exercise over our internally developed intellectual property. We do not control the prosecution of certain of the patent applications that we license from third parties; therefore, the patent applications may not be prosecuted exactly as we desire or in a timely manner.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

we or our licensors were the first to make the inventions covered by each of our pending patent applications;

we or our licensors were the first to file patent applications for these inventions;

the patents of others will not have an adverse effect on our ability to do business;



## Table of Contents

others will not independently develop similar or alternative technologies or reverse engineer any of our products, processes or technologies;

any of our pending patent applications will result in issued patents;

any patents issued or licensed to us or our collaborators or strategic partners will provide a basis for commercially viable products or will provide us with any competitive advantages;

any patents issued or licensed to us will not be challenged and invalidated by third parties; or

we will develop additional products, processes or technologies that are patentable.

Others have filed and in the future are likely to file patent applications that are similar to ours. We are aware that there are academic groups and other companies that are attempting to develop technology that is based on the use of zinc finger and other DNA-binding proteins, and that these groups and companies have filed patent applications. Several patents have been issued, although we have no current plans to use the associated inventions. If these or other patents issue, it is possible that the holder of any patent or patents granted on these applications may bring an infringement action against our collaborators, strategic partners, or us claiming damages and seeking to enjoin commercial activities relating to the affected products and processes. The costs of litigating the claim could be substantial. Moreover, we cannot predict whether we, our collaborators, or strategic partners would prevail in any actions. In addition, if the relevant patent claims were upheld as valid and enforceable and our products or processes were found to infringe the patent or patents, we could be prevented from making, using, or selling the relevant product or process unless we could obtain a license or were able to design around the patent claims. We can give no assurance that such a license would be available on commercially reasonable terms, or at all, or that we would be able to successfully design around the relevant patent claims. There may be significant litigation in the genomics industry regarding patent and other intellectual property rights, which could subject us to litigation. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources.

We cannot guarantee that third parties will not challenge our intellectual property. One of our in-licensed foreign patents, licensed to Sangamo from Johns Hopkins University which forms the basis for five European Regional Phase patents, has been revoked as a result of an opposition by a third party. Our licensor, The Johns Hopkins University, appealed the revocation but in April 2007, the European Technical Board of Appeal released its decision dismissing the appeal. This outcome may limit our ability to exclude potential competitors in the field of targeted recombination and gene correction in Europe but does not affect our ability to practice our targeted recombination and gene correction programs in Europe. Moreover, we also hold licenses to six US patents to the technology covered by the opposed European patent, and hold licenses to related applications pending in Canada and Japan. As of January 25, 2008, US patent numbers US5,792,640 and US6,265,196, licensed to Sangamo from The Johns Hopkins University, were undergoing re-examination, and we do not know what the outcome of the process will be.

We rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. Trade secrets, however, are difficult to protect. While we require employees, academic collaborators, and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information or enforce these confidentiality agreements.

Our collaborators, strategic partners, and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations and strategic partnerships, then we may not be able to receive patent protection or protect our proprietary information.

### ***Failure to attract, retain, and motivate skilled personnel and cultivate key academic collaborations will delay our product development programs and our research and development efforts.***

We are a small company with 81 full-time employees as of May 1, 2008 and our success depends on our continued ability to attract, retain, and motivate highly qualified management and scientific personnel and our ability to develop and maintain important relationships with leading research and academic institutions and scientists. Competition for personnel and academic and other research collaborations is intense. The success of our technology development programs depends on our ability to attract and retain highly trained personnel. We have experienced a rate of employee turnover that we believe is typical of emerging biotechnology companies. If we lose the services of personnel with the necessary skills, it could significantly impede the achievement of our research and development objectives. We are not presently aware of any plans of specific employees to retire or otherwise leave the company. If we fail to negotiate additional acceptable collaborations with academic and other research institutions and scientists, or if our existing collaborations are unsuccessful, our ZFP Therapeutic development programs may

be delayed or may not succeed.

---

## **Table of Contents**

***If conflicts arise between us and our collaborators, strategic partners, scientific advisors, or directors, these parties may act in their self-interest, which may limit our ability to implement our strategies.***

If conflicts arise between our corporate or academic collaborators, strategic partners, or scientific advisors or directors and us, the other party may act in its self-interest, which may limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates.

Some of our collaborators or strategic partners could also become competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

***If we do not successfully commercialize ZFP based research reagents under our license agreement with Sigma-Aldrich Corporation, or if Sigma terminates our agreement, our ability to generate revenue under the license agreement may be limited.***

On July 10, 2007, we entered into a license agreement with Sigma to collaborate in the application and development of ZFP-based products for use in the laboratory research reagents markets. The license agreement provides Sigma with access to Sangamo's ZFP technology and the exclusive right to use Sangamo's ZFP technology to develop and commercialize products for use as research reagents and to offer services in related research fields. In addition to an upfront payment of \$13.5 million, Sangamo may also receive additional license fees, shared sublicensing revenues, royalty payments and milestone payments depending on the success of the development and commercialization of the licensed products and services. The commercial milestones and royalties are based upon net sales of licensed products. We believe that the last commercial milestone payment may not be received before 2011. Our right to receive royalty payments from Sigma will continue until the later of (i) the expiration of the last to expire valid claim of such licensed product and (ii) the 15th anniversary of the effective date of the License Agreement. We cannot be certain that Sigma and Sangamo will succeed in the development of commercially viable products in these fields of use, and there is no guarantee that Sangamo and Sigma will achieve the milestones set forth in the license agreement. To the extent Sangamo and Sigma do not succeed in developing and commercializing products or if Sangamo and Sigma fail to achieve such milestones, our revenues and benefits under the license agreement will be limited. In addition, the license agreement may be terminated by Sigma at any time by providing us with a 90-day notice. In the event Sigma decides to terminate the license agreement, our ability to generate revenue under the license agreement will cease.

***If we do not successfully commercialize certain ZFP Therapeutic programs relating to diabetic neuropathy under our agreement with JDRF, JDRF may have the right to continue to advance the program and we may lose control of the intellectual property generated in the collaboration and development of the product and may only receive a portion of the revenue generated if commercialization by JDRF is successful.***

On October 24, 2006, we entered into a Research, Development and Commercialization Agreement with JDRF. Under the agreement and subject to its terms and conditions, including our achievement of certain milestones associated with our Phase 2 clinical trial of SB-509 (SB-509-601) for the treatment of diabetic neuropathy, JDRF has paid us a total of \$2.5 million through December 31, 2007. We are obligated to cover the costs of the Phase 2 trial that are not covered by JDRF's grant.

Under the agreement, we are obligated to use commercially reasonable efforts to carry out the Phase 2 trial and, thereafter, to develop and commercialize, a product containing SB-509 for the treatment of diabetes and complications of diabetes. If we fail to satisfy these obligations, JDRF may have the right, subject to certain limitations, to obtain an exclusive, sublicensable license, to the intellectual property generated by us in the course of the Phase 2 trial, to make and commercialize products containing SB-509 for the treatment of diabetes and complications of diabetes. If JDRF obtains such a license, it is obligated to pay us a percentage of its revenues from product sales and sublicensing arrangements. If JDRF fails to satisfy its obligations to develop and commercialize a product containing SB-509 under the Agreement, then their license rights will terminate and we will receive a non-exclusive, fully paid license, for any intellectual property developed during JDRF's use of the license, to research, develop and commercialize products containing SB-509 for the treatment of diabetes and complications of diabetes. There is no guarantee that we will be successful in commercializing a product containing SB-509 in the future. If we fail to do so under the agreement with JDRF, we may lose control of the intellectual property generated in the development of the product and may only receive a portion of the revenue generated if commercialization by JDRF is successful.



## **Table of Contents**

***Regulatory approval, if granted, may be limited to specific uses or geographic areas, which could limit our ability to generate revenues.***

Regulatory approval will be limited to the indicated use for which we can market a product. Further, once regulatory approval for a product is obtained, the product and its manufacturer are subject to continual review. Discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer, and manufacturing facility, including withdrawal of the product from the market. In Japan and Europe, regulatory agencies also set or approve prices.

Even if regulatory clearance of a product is granted, this clearance is limited to those specific states and conditions for which the product is useful, as demonstrated through clinical trials. We cannot ensure that any ZFP Therapeutic product developed by us, alone or with others, will prove to be safe and effective in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing clearance in a given country.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities, so we cannot predict whether or when we would be permitted to commercialize our product. These foreign regulatory approval processes include all of the risks associated with FDA clearance described above.

***Our collaborations with outside scientists may be subject to change, which could limit our access to their expertise.***

We work with scientific advisors and collaborators at academic research institutions. These scientists are not our employees and may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. Although our scientific advisors and academic collaborators sign agreements not to disclose our confidential information, it is possible that some of our valuable proprietary knowledge may become publicly known through them, which may cause competitive harm to our business.

***Laws or public sentiment may limit the production of genetically modified agricultural products in the future, and these laws could reduce our partner's ability to sell these products.***

Genetically modified products are currently subject to public debate and heightened regulatory scrutiny, either of which could prevent or delay production of agricultural products. Effective as of October 1, 2005, we entered into a Research License and Commercial Option Agreement with DAS. Under this agreement, we will provide DAS with access to our proprietary ZFP technology and the exclusive right to use our ZFP technology to modify the genomes or alter the nucleic acid or protein expression of plant cells, plants, or plant cell cultures. The field-testing, production, and marketing of genetically modified plants and plant products are subject to federal, state, local, and foreign governmental regulation. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of our genetically modified products in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our product development programs or the commercialization of resulting products.

The FDA currently applies the same regulatory standards to foods developed through genetic engineering as those applied to foods developed through traditional plant breeding. Genetically engineered food products, however, will be subject to pre-market review if these products raise safety questions or are deemed to be food additives. Governmental authorities could also, for social or other purposes, limit the use of genetically modified products created with our gene regulation technology.

Even if we are able to obtain regulatory approval for genetically modified products, our success will also depend on public acceptance of the use of genetically modified products including drugs, plants, and plant products. Claims that genetically modified products are unsafe for consumption or pose a danger to the environment may influence public attitudes. Our genetically modified products may not gain public acceptance. The subject of genetically modified organisms has received negative publicity in the United States and particularly in Europe, and such publicity has aroused public debate. The adverse publicity in Europe could lead to greater regulation and trade restrictions on imports of genetically altered products. Similar adverse public reaction in the United States to genetic research and its resulting products could result in greater domestic regulation and could decrease the demand for our technology and products.

---

**Table of Contents**

*If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.*

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals, and various radioactive compounds typically employed in molecular and cellular biology. We routinely use cells in culture and gene delivery vectors, and we employ small amounts of radioisotopes in trace experiments. Although we maintain up-to-date licensing and training programs, we cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling, or disposal of these materials. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our resources. We currently carry insurance covering claims arising from our use of these materials. However, if we are unable to maintain our insurance coverage at a reasonable cost and with adequate coverage, our insurance may not cover any liability that may arise. We are subject to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. To date, we have not experienced significant costs in complying with regulations regarding the use of these materials.

*Anti-takeover provisions in our certificate of incorporation and Delaware law could make an acquisition of the Company more difficult and could prevent attempts by our stockholders to remove or replace current management.*

Anti-takeover provisions of Delaware law and in our certificate of incorporation and our bylaws may discourage, delay or prevent a change in control of our company, even if a change in control would be beneficial to our stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. In particular, under our certificate of incorporation our board of directors may issue up to 5,000,000 shares of preferred stock with rights and privileges that might be senior to our common stock, without the consent of the holders of the common stock. Moreover, without any further vote or action on the part of the stockholders, the board of directors would have the authority to determine the price, rights, preferences, privileges, and restrictions of the preferred stock. This preferred stock, if it is ever issued, may have preference over, and harm the rights of, the holders of common stock. Although the issuance of this preferred stock would provide us with flexibility in connection with possible acquisitions and other corporate purposes, this issuance may make it more difficult for a third party to acquire a majority of our outstanding voting stock. Similarly, our authorized but unissued common stock is available for future issuance without stockholder approval.

In addition, our bylaws:

state that stockholders may not act by written consent but only at a stockholders meeting;

establish advance notice requirements for nominations for election to the board of directors or proposing matters that can be acted upon at stockholders meetings; and

limit who may call a special meeting of stockholders.

We are also subject to Section 203 of the Delaware General Corporation Law, which provides, subject to certain exceptions, that if a person acquires 15% of our voting stock, the person is an interested stockholder and may not engage in business combinations with us for a period of three years from the time the person acquired 15% or more of our voting stock.

*Insiders have control over Sangamo and could delay or prevent a change in corporate control.*

The interest of management could conflict with the interest of our other stockholders. Our executive officers and directors beneficially own, in the aggregate, approximately 13% of our outstanding common stock as of March 17, 2008. As a result, these stockholders, if they choose to act together, may have a material impact on all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change of control of Sangamo, which in turn could reduce the market price of our stock.

**Table of Contents**

**ITEM 6. EXHIBITS**

(a) Exhibits:

- 10.1 (+) Second Research and License Agreement dated as of February 27, 2008 between Genentech, Inc., and Sangamo BioSciences, Inc.
- 10.2 (+) Letter Agreement dated February 25, 2008 between Sigma-Aldrich Corporation and Sangamo BioSciences, Inc.
- 31.1 Rule 13a 14(a) Certification by President and Chief Executive Officer
- 31.2 Rule 13a 14(a) Certification by Principal Financial and Accounting Officer
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350.
- (+) Confidential treatment has been requested for certain information contained in this document. Such information has been omitted and filed separately with the Securities and Exchange Commission.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SANGAMO BIOSCIENCES, INC. Dated: May 9, 2008

/s/ H. Ward Wolff  
H. Ward Wolff  
Executive Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)